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To Whom It May Concern:

Analog Hair Care Analysis Inc. is a wholly owned subsidiary of Nisim International. The various terms to products in the following documents are in fact the Original Hair and Scalp Stimulating Extract and the Gel Hair and Scalp Stimulating Extract solutions currently sold by Nisim International. These include: Analog Regrowth Treatment; All Natural Compound; Natural Compound Solution and any other reasonable variations of the descriptions as they may appear.

At the time of testing, the trade names of the Extracts did not exist. "Hair Regrowth" was only an in house reference name.

Furthermore the term(s): Specially formulated scalp cleanser; Scalp Cleanser, Shampoo in these documents refers to the Normal to Oily and Normal to Dry NewHair Biofactors Shampoos (including the No Sulfates, Parabens, DEA Shampoos). Both the Shampoos contain IDENTICAL ACTIVES to each other. Both Scalp Extracts contain IDENTICAL ACTIVES to each other. Due to this fact a further breakdown of type of shampoo and type of Scalp Extracts used in the Studies was not deemed relevant and was not recorded.

Sincerely,

NISIM INTERNATIONAL

John Nikolaou
President

510 Applewood Cres.
Vaughan, ON
Canada L4K 4B4

P: 905.532.0773
F: 905.532.9744

TF: 1.800.656.4746
www.nisim.com

Effect of Topical Application

of an

All Natural Compound Solution

on

Male Pattern Baldness

A. J. Farmilo, Ph D.

M. A. Stratis, R.T.

J. S. McGrail, M.D. M.S. F.R.C.S.(C)

H. L. Minuk, M.D. F.R.C.P.(C) A.B.I.M.

SUMMARY

One-hundred-and-forty-eight participants with varying degrees of male pattern baldness (androgenic alopecia) from Stage III to Stage VIII, participated in an open-ended study using an all natural compound solution to determine the effects of hair re-growth.

The participants were photographed and initial hair counts were done in a 2.5cm diameter area of their balding scalp. After five months of treatment the participants were re-photographed and hair counts were done on the same 2.5cm diameter area of the scalp. The results indicate that 85.7% of the men in the study had an increase in their terminal hairs of 30% or greater. When evaluating the percent increase more closely we find that we can break the data down into three separate groups:

1. Significant re-growth.
2. Moderate re-growth.
3. No change.

The group showing a significant re-growth was 40.8% of the study group, and had an increase of 100% or greater (doubling, tripling or more) of terminal hairs counted on their five month post-treatment photo and compared to their initial pre-treatment photo. Of this group the highest increase of hairs was 472%, the lowest increase was 102% with mean at 193.7% increase of hairs.

The group of men showing moderate re-growth, which we classed as 30%-100% increase in terminal hair re-growth, was 44.9% of the study group. The mean increase of that group was 61.5% increase of hair re-growth.

The remainder of the group, classed as no change, was 14.3% of the study group, with the range being minus 13% to +27% increases in hair counts with the mean at 6.7%.

The participants were also classed according to their degree of baldness using Hamilton's classification scheme (See Figure #1) Class IV balding men showed the greatest percent increase at an overall average of 144% more terminal hairs than pre-treatment, with Classes V and VI both slightly less at approximately 120% average increase. Class VII and VIII responded the poorest at 102% and 65% average increases respectively.

Another factor considered was the amount of treatment used during the study. The participants were told to use at least one bottle per month (five bottles in five months) but were allowed to use more if desired. We did not see and significant advantage to using more than one bottle per month. Our conclusion is that the stimulatory effect of the compound is achieved at the use rate of one bottle per month.

The age range of the participants in the ability to re-grow hair was not a factor. The range of the participants in this study was 24-68 years old, with the average age being 38.7 years.

In summary, this study concludes that the Analog Compound has a stimulatory effect on hair growth for at least 8 out of 10 men with androgenic alopecia. The earlier stages of balding appear to respond to a higher degree, but significant improvement was seen in participants at all stages of baldness. There appears to be an optimum rate of use of the product, and age does not seem to be a factor in response. Further studies are being carried out to determine significant factors in the response to the treatment, and to analyze the mechanism of action of the compound.

INTRODUCTION

Hair performs no vital function relative to the medical well being of humans. Yet the psycho-social implications can never be underestimated. Scalp hair can be the crowning glory for the femininity of women and a potent symbol of masculinity and security in men.

Hair consists of a cylinder of impacted, keratinized cells. The hair, together with the 3-layered inner root sheath is formed by the division of cells in the matrix which surrounds the dermal papilla (7, 10). Hair growth varies from individual to individual and from various regions of the body (7).

The correlation of body hair and hormones has long been established as the major cause of balding in men and hirsutism in women (5, 12, 15, 16). The interaction between androgenic hormones like dihydrotestosterone (DHT), receptor sites and the scalp have been a fascinating area of research. At the cellular level, androgens like DHT are transported into the cytoplasm, attached to a cytosol receptor, and are then translocated as a hormone-receptor complex, to the nucleus of the target cells (5, 12, 15). We know the action of testosterone involves the reduction of the hormone itself to DHT by the reducing enzyme 5-alpha reductase (19, 20). Several theories of anti-androgenic action have been put forward to prevent the production of DHT or the binding of DHT to its receptor sites:

1)   Inhibit or block the production of the 5-alpha reductase enzyme from acting on testosterone (20) or;

2)   prevent the binding of DHT to its target cells by a competitive non androgenic substance (15, 20).

The reversal of male pattern baldness (androgenic alopecia) in men has for century's eluded science and medicine. Minoxidil and Diazoxide have shown in past studies to reverse

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alopecia in men, although in only small percentages of the patients studied (1, 2, 3, 4, 13, 14).

Other scientific studies done on controlled groups of balding or thinning men was the "Pulsed Electrostatic Field" experiment that reported a good percentage of hair re-growth, but required constant weekly visits to medical offices, thus limiting its universal acceptance (8).

This study demonstrated the safety and efficacy of a natural compound solution to stimulate hair growth. The solution is coupled with a treatment regimen which includes scalp cleansing and proper scalp massaging. This treatment is demonstrated at the Analog Clinic with proper instructions and can then be performed at home.

PATIENTS AND METHODS

One hundred and sixty four males with male pattern baldness from the greater Toronto area were studied at the Analog hair clinic. After informed consent, past medical histories and years of balding, the men were selected. Patients that were using any form of corticosteroids, cytotoxic agents or any other form of hair re-growth agents like minoxidil were excluded from the study. In this study all stages of Hamilton's classification of male pattern baldness were used and none were excluded (6).

Since the methodology involved in this study includes proper scalp cleansing and massaging of the scalp along with the all natural compound solution, it was difficult for us to establish a relevant placebo. The other problem in establishing a relevant placebo was the lack of knowledge of the active ingredients (producing the hair re-growth) in the all natural compound solution, thus it was decided to run an open-ended study.

All men were instructed and shown very carefully how to use the specially formulated scalp cleanser and all natural compound solution. Once this was handled all the men were photographed with a high resolution Minolta "instant pro" camera. The room was brightly illuminated for close examination of the scalp and individual hair(s). The same room and chair were going to be used throughout the duration of the study. The camera was position exactly 25cm from the balding or thinning areas with frontal, top and rear pictures taken as needed. The participants were asked to wait for the picture to develop and sign their respective photos along with the current date.

Administration and Dosage

The all natural compound solution was supplied at no charge to the participants. Each person received 250ml of the alcohol based all natural compound solution along with 250ml of a

specially formulated deep scalp cleanser. They were all individually and carefully instructed on the proper usage of both the scalp cleanser and all natural compound solution. The stressed importance of proper hygiene and regular application was duly emphasized. All participants were instructed to apply the solution at least three times a day, to the balding or thinning areas of their scalp. They were told to apply 2-3ml of the solution on each application and were further instructed how to massage the scalp firmly.

Classification of male pattern baldness (See Figure #1)

Evaluation and Assessment Grading

The photos taken prior to the treatment were closely evaluated and graded according to Hamilton's classification (See Figure #1). Before the treatment was initiated, a 2.5cm circle in diameter was drawn in the balding area, always very near the border of the area demonstrating the most significant hair loss. The circle was located with reference to a precise three point measurement using the bridge of the nose and the intersection of a line drawn using the midway point between the tops of each ear. Initial hair counts were done using 4 X magnifying lens mounted on a circular fluorescent lamp. Independent counts were made by two of us (MS and AJF), times 2, and the average of the two counters were used for statistical purposes. The hairs in the 2.5cm area were counted, including hairs on the circular boundary. The final counts on the participants were done after five (5) months on the treatment program. The same criteria established from the initial photograph was used to determine the exact location of the 2.5cm

area on the scalp and the same procedure was used to count hair roots within and on the boundary of the inscribed circular area.

For the participants in which their photos prior to or after five months of treatment were not countable, a qualitative analysis was done. At the conclusion of the five (5) month treatment program, the photos were graded under the following categories:

A zero (0) grading was given to the photos that revealed no change from their initial pre-treatment photo.

A grading of one (1) was given to the participants with moderate re-growth of hair from their respective original photos.

And a grading of two (2) was assigned to the men with a significant re-growth of hair from their original photos.

This qualitative assessment was made by one person on two different days and, was checked by a second qualified person. The results were found to be consistent between the two graders.

Figure 1; Male pattern baldness according to classification or stage.
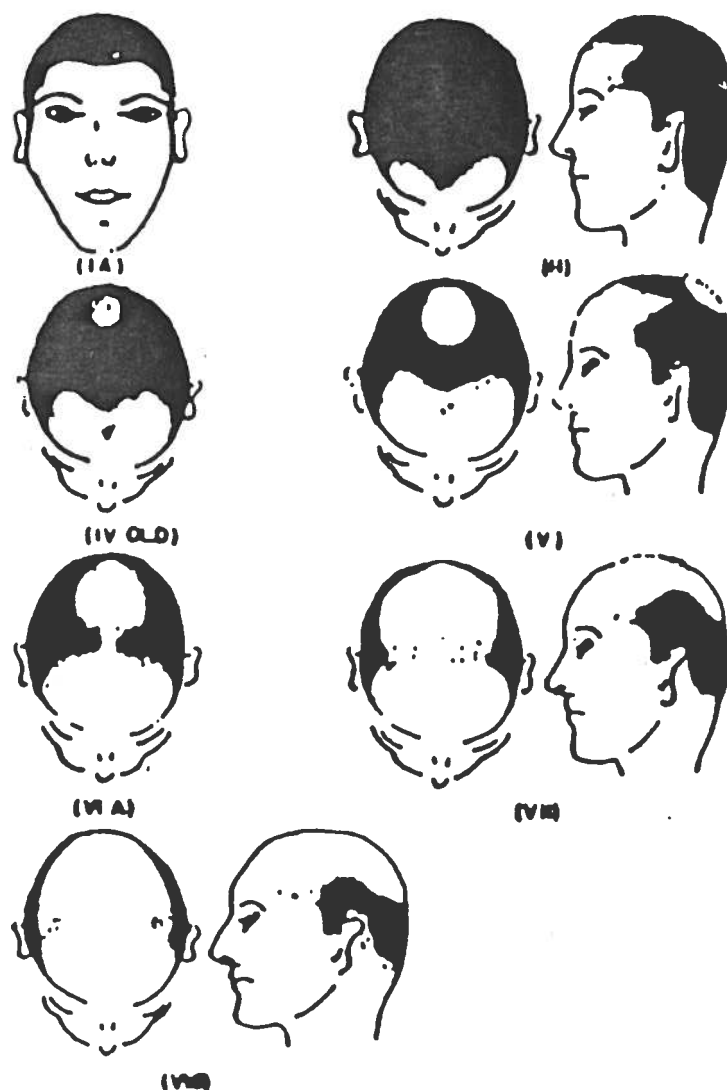
RESULTS

Of the one hundred and sixty-four participants starting the study, eleven were eliminated because of their repeated absence from photo sessions, and failure to use the product. Four were eliminated due to their irregular use of both the scalp cleanser and the all natural compound solution, and one person was discontinued because he relocated to another country. The remainder of the 148 participants applied the all natural compound solution at least twice daily for the five months as required for this study. The participants have committed themselves for at least another three more months of treatment enabling us to do further quantitative analysis after eight months of treatment.

The re-growth of hair was first noticed on some participants as early as two months into the treatment. By the third month, a substantial number of men demonstrated moderate re-growth; both fine vellus hair (peach fuzz) and darker pigmented intermediate and terminal hairs were observed. It is noteworthy to mention that the fine vellus hairs, although visible to the naked eye, were not detectable by the photos. Thus all of our quantitative and qualitative assessments were made from any intermediate and/or terminal hairs.

Criteria for Analysis of Response to All Natural Compound Solution

Of the 148 participants, 98 had discrete balding areas that allowed us to perform individual hair counts before and after the treatment. The percent increases or decreases were recorded along with other data that was accumulated during the study. The remaining 50 participants were graded qualitatively and graded as discussed previously. The results were analyzed with two major group headings of participants, one with actual hair counts and the second group with no hair counts.

The group that had actual hair counts done had to be closely evaluated and we had to determine the percentage increase that we considered re-growth. In order to account for the human error in counting the hairs the mean standard deviation between the two counters was determined on all the counts, and was calculated to be +/- 7.38%. Using the 7.38% figure, we calculated 2X the standard deviation of pre-treatment and five month post-treatment counts and determined that participants with less than 29.52% increase in intermediate and/or terminal hairs were counted as no change. This correlated well with no substantial hair re-growth in the corresponding participants photograph. The moderate improvement group we determined were the men that showed an increase of final hair counts of greater than 30% and up to 100% increases of terminal hairs, in their five month photos as compared to their original photos. Their photographic change was more noticeable and also correlated well with their relative percentage increase. The last group we identified was the significant increase group, this group showed the best improvement of all the men in the study and we included those with hair count increases of 100% or greater.

Response of the All Natural Compound Solution on Baldness

Although the qualitative and quantitative assessments were done independently, there was a strong correlation between the two groups (See table #1). Overall, 88% of the qualitative group showed some degree of improvement. Of the group studied quantitatively, 85.7% showed a degree of re-growth (within 95% confidence limits). With the qualitative group, 6 of the 50 men were categorized as having no change (category 0), representing 12% of the total. The quantitative group (98 participants), 14 men or 14.3% did not show any increase in hair counts. The range of hair count increases for this group was (minus) -13% to +27%, with the mean

being 6.7%. The photographs of these participants did not show any visible improvement of hair growth.

The moderately improved qualitative group (category 1), consisted of 16 participants or 32%. In the quantitatively studied group, 44 of the 98 men fell into the range of +30% to +100%. This represents 44.9% of the men. The range of increase was 32% to 98%, with the mean at 61.5%. The participants showing significant re-growth in the qualitative group (category 2), was 28 of 50, or 56%. In the quantitatively studied group, the number of men with significant re-growth (greater than 100%) was 40 of 98, or 40.8%. These men had hair count increases of 100% or more. The range of hair count increases was 102% to 472%, with a mean increase of 194%. The photograph of these men showed significant cosmetic changes which correlates very well with our quantitative findings.

Product Safety and Sensitivity Studies

The all natural compound solution had been subjected to the following safety and sensitivity studies:

        I)   The Mutagenesis Assay also known as the Modified Ames Assay.

        II)   The Guinea Pig Dermal Photosensitivity and Photoallergenicity study.

        III)   The Rat Oral LD_{50} Determination test.

The final test results of the all natural compound solution show the solution to be "non mutagenic", non-phototoxic/photoallergenic and no gross pathological changes were found at the end of the Rat Oral LD_{50} study. The LD_{50} was in excess of 5.0 grams, (5.52ml) per kilogram of body weight.

Photo 1; Photograph of pretreatment male showing baldness.

Photo 1A; Photograph of the same male as in Photo 1, five months after treatment showing no change.

Photo 2; Photograph of pretreatment male showing baldness.

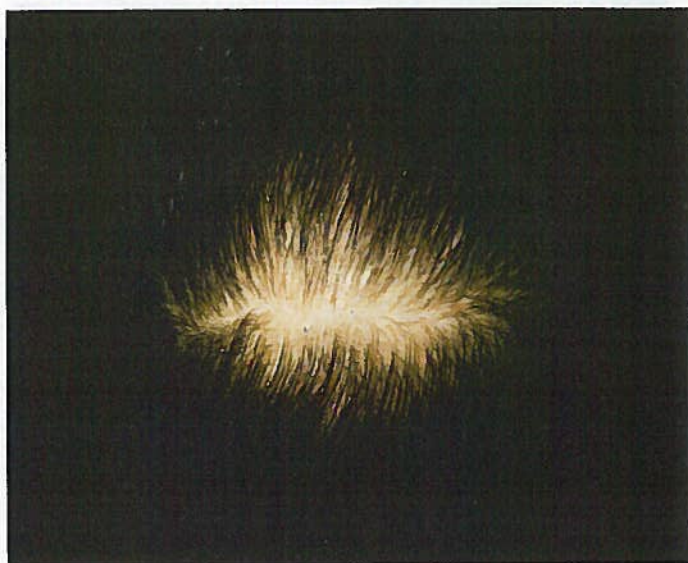Photo 2A; Photograph of the same male as in Photo 2, five months after treatment showing moderate regrowth.

Photo 3; Photograph of pretreatment male showing baldness.

Photo 3A; Photograph of the same male as in Photo 3, five months after treatment showing significant regrowth.

Photo 4; Photograph of pretreatment male showing baldness.

Photo 4A; Photograph of the same male as in Photo 4, five months after treatment showing significant regrowth.

Photo 5; Photograph of pretreatment male showing baldness.

Photo 5A; Photograph of the same male as in Photo 5, five months after treatment showing significant regrowth.

TABLE #1: DISTRIBUTION OF STUDY PARTICIPANTS BY RESPONSE.

CATEGORY	QUALITATIVE GROUP	PERCENT	QUANTITATIVE GROUP	PERCENT
NO CHANGE	6	12%	14	14.3%
MODERATE	16	32%	44	44.9%
SIGNIFIGANT	28	56%	40	40.8%
TOTAL	50	100%	98	100%

Correlation of Response with Duration of Baldness

There appeared to be no correlation between the efficacy of the product and the duration of baldness. The lowest increase was 89% in the group with over 20 years of balding, followed by a 107% increase in the group balding for 6-10 years. The highest increase of 149% occurred in the group balding for 16-20 years. However, the standard deviation of these values range from 30-70% of the counts, so there is no statistical significance between these values. Assessing the results by the population groupings (no change, moderate change, and significant change), similarly shows no outstanding trends (See Figure #2).

Correlation of Response with Initial Hair Count

The mean initial hair count for the group which showed no increase the mean was 28 (range 10-86), and for the group which showed significant increase the mean was 26 (range 7-58). There is no statistically significant difference between the mean initial hair counts of any of the three groups studied as a function of initial hair counts (See Figure #3), a higher percentage of significant growth occurred in the participants with initial hair counts in the under 30 range (52 +/-14%) than in the participants with initial hair counts over 30 (24 +/-11%). These data imply that although there does not seem to be any relationship between the initial hair counts and the efficacy of the product, there may be a higher chance of significant changes in individuals with lower initial hair counts. This effect could be just a "ceiling" on the total number of hairs which re-grow, thus giving a high percentage increase of those individuals starting from a low number.

Pattern of Hair Re-growth

From those photos taken monthly during the course of the study, a pattern of re-growth was observed in those participants who demonstrated a significant increase in hair counts over the five months. The first countable hairs were seen after 10-12 weeks of treatment and were first detected on the crown or vertex of the head. Following further treatment, hair was then observed re-growing in the margin or fringe of the thinning or balding areas of the scalp. Hair re-growth in the fronto-temporal region of the scalp was noted after 16-20 weeks of treatment, and this region appeared to be the most resistant to re-growth to date. We suspect that 8-12 months further into the treatment, better conclusions can be reached as to the full extent at which the product can diminish whole areas of balding.

Correlation of Response with the Amount of Product Used

Participants were grouped according to the number of bottles of product used during the five month period of the study. Since each bottle contained 250ml of product, and the recommended rate of use was 5-10ml twice daily, the expected use rate over the five months was 1500-3000ml (6-12) bottles, or 250-500ml/month (1-2 bottles/month). However, the participants were allowed by the study to use as much of the product as they wished, and the range of product consumption was 750-6500ml over the course of the study, or 250-1300ml/month. Data correlating the response with rate of use are shown in Figures #4 and #5. Figure #4 shows the response based on the monthly use rate, and indicates that the best response occurs with the use of 250-750ml/month. Figure #5 shows the population statistics for these data. Participants have a 46 +/-3% chance of a significant change when using between

250-750ml/month, but only a 25 +/-8% chance of significant change when using more than 750ml/month. From these data, it appears that there is likely a maximum effective dose of the product, probably in the 250-750ml/month range, and that excessive use of the product does not help the response rate.

Correlation of Response with Stage of Baldness

The results for qualitative and quantitative measured groups were assessed separately for the purposes of this evaluation. From the qualitatively assessed group, the results are shown in Table 2 and Figure 6. The participants with stages IV and V baldness had the best cosmetic (qualitative) result, with an average of 70% showing a significant improvement. The participants with stages III, and VI and VII/VIII had a much lower percentage showing a significant increase of only 18%, although those at stage III and VI showed a moderate cosmetic improvement in 30-40% of the cases.

The data from the quantitative results are shown in Table 3 and Figure 7. The data measured from these participants appears to be, on the whole, consistent with the results obtained from the qualitatively measured group, but show much less dramatic changes between the different stages. Stage IV appears to have a much lower response rate in the significant re-growth category (11% compared to 63%), and a much higher response rate in the moderate category (78% compared to 37%). Conversely, the response rate for stages VII and VIII appear to be much higher in the quantitative measurements than in the qualitative assessments. However we could conclude that participants at all stages of baldness have a chance of responding to the treatment, with those at stages III, IV, V, and VI probably showing the most significant overall improvements.

Correlation of Response with Age

The average age of the 176 participants was 38.7 years. The mean ages for their respective groups were as follows:

The no change group was 41.8 years.

Moderate group was 36.7 years.

Significant group was 38.5 years.

The youngest participant in the study was 22 years old and the oldest participant was 63. There was no correlation between age and response to treatment.

TABLE #2: QUALITATIVELY ASSESSED GROUP

STAGE	TOTAL No. MEN	% NO CHANGE	% MODERATE CHANGE	% SIGNIFICANT CHANGE
III	10	20%	60%	20%
IV	19	0%	37%	63%
V	13	8%	15%	77%
VI	6	33%	33%	33%
VII/VIII	2	100%	0%	0%

TABLE #3: QUANTITATIVELY ASSESSED GROUP

STAGE	TOTAL No. MEN	% NO CHANGE	% MODERATE CHANGE	% SIGNIFICANT CHANGE
IV	9	11%	78%	11%
V	30	10%	40%	50%
VI	34	18%	47%	35%
VII	15	0%	40%	60%
VIII	10	40%	30%	30%

DISCUSSION

This open-ended study has demonstrated the hair re-growth response of 148 men who have been treated with an all natural compound solution applied topically to balding or thinning regions of the scalp. The treatment program included regular scalp cleansing with a natural extract scalp cleanser and application of at least 5-10ml of the all natural compound solution at least twice daily. The data showed that hair counts increased significantly for approximately 85% of the participants in the five-month period. Further studies determining the requirement to continue this treatment are planned.

The study methodology implies that the results obtained relate not only to the all natural compound solution used in the treatment, but also the overall treatment regimen. From previous minoxidil papers (2, 21) it was determined by them that a reasonable expectation for a "placebo-type" effect was a 10-15% increase in hair counts. Thus, by setting the cut-off in this study for moderate re-growth at a 30% increase, any increase due to a "placebo-type" effect is discounted.

An attempt was made to correlate the response (either no change, moderate change or significant change) with a number of factors. None of the factors studied gave a strong correlation, although there were some trends noted. The number of years of balding or thinning hair did not appear to have any correlation with the final results. However, it should be noted that the number of years thinning was a number given by the participants and could not be verified accurately. Thus it is a subject of assessment and may not be very reliable. To help balance this uncertainty, the results were grouped. Regardless of the groupings used, there was no grouping which demonstrated a significant correlation with results. This differs from the De

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Villez study (2), in which the suggestion is made that the individual most likely to benefit from topical minoxidil treatments was bald less than five years, had a smaller diameter (less than 10cm) of balding area, and had greater than 100 intermediate hairs in the centre of the balding area. The difference probably results from the method used to determine the area of hair counts in our study. The area counted was always on the edge of the balding area, or in an area with some countable hairs. For the quantitative studies, balding of the type described by De Villez would have been excluded since it was difficult to count accurately more than 150 hairs in the 2.5cm diameter circle. Thus these individuals would have fallen into our qualitative assessed group. Another difference probably arises from the fact that this study will count hairs in the prescribed area regardless of the overall cosmetic effect. An individual who starts with 9 hairs, and increases to 36 hairs would have a 400% increase, and yet the cosmetic effect may not be very significant.

The correlation of response with balding pattern provided an insight that the response might be related to the extent that the cosmetic effect was best at the earlier stages of baldness, and the percentage increase in hair counts was most significant at the middle stages of baldness. This is not unexpected, and it is hoped that this correlation will be proved or disproved during the extension of this study.

The correlation between response and rate of use of the product also demonstrated a maximum effective use rate for the product. This implies that whatever action is resulting in hair re-growth occurs at a certain treatment level, and then cannot be enhanced by additional treatments. This result is subject to the fact that the participants in the study are expected to perform the treatments correctly and consistently. Each participant was shown two to three times how to do the treatments, and each had treatments done in the clinic at their photo

intervals each month. This kept a certain control over the application of the product. However, there may be errors in use which would cloud the data in this study.

The mechanism by which the all natural compound solution stimulates hair re-growth is not known. Further studies are currently under way to determine any histological changes on the balding scalp biopsies before and after treatment. The area of particular interest in the ensuing study is to determine if the all natural compound solution has any anti-androgenic properties (15, 20). Medical scientists have been aware that there may be a genetic tendency towards androgenic alopecia (5, 6, 12), but its action is still not entirely clear. Testosterone or DHT, play a role in hair loss, as does blood flow, stress and a number of other factors (6, 7, 20).

Studies have shown the effects of minoxidil and its metabolites at the cellular level, from the point of view of stimulated cell division and cell metabolism and also played a role as a potassium channel opening agent (13). Which of these effects are responsible for hair growth is not clear. Results from subsequent studies to be reported later may show a role of this all natural compound solution in cell division and metabolic activity.

In terms of hair re-growth, this all natural compound solution appears to be more effective than minoxidil and has no known side effects. A study by Alanis, et al (21) showed that a 2% minoxidil preparation applied topically increased hair counts by about 24% after 20 weeks. This study showed an increase of 89% in the same time period. Because of the differences in locating the measured regions of the scalp, these results are not directly comparable, but in a population study, Alanis' results showed that 34-46 out of 83 participants (48%) had no growth after 24 weeks, whereas our results show only 14 out of 98 (14%) had no growth after 20 weeks. Thus our conclusion is that this product does stimulate re-growth of hair

in cases of androgenic alopecia, and that over 85% of men will respond favorably to the treatment.

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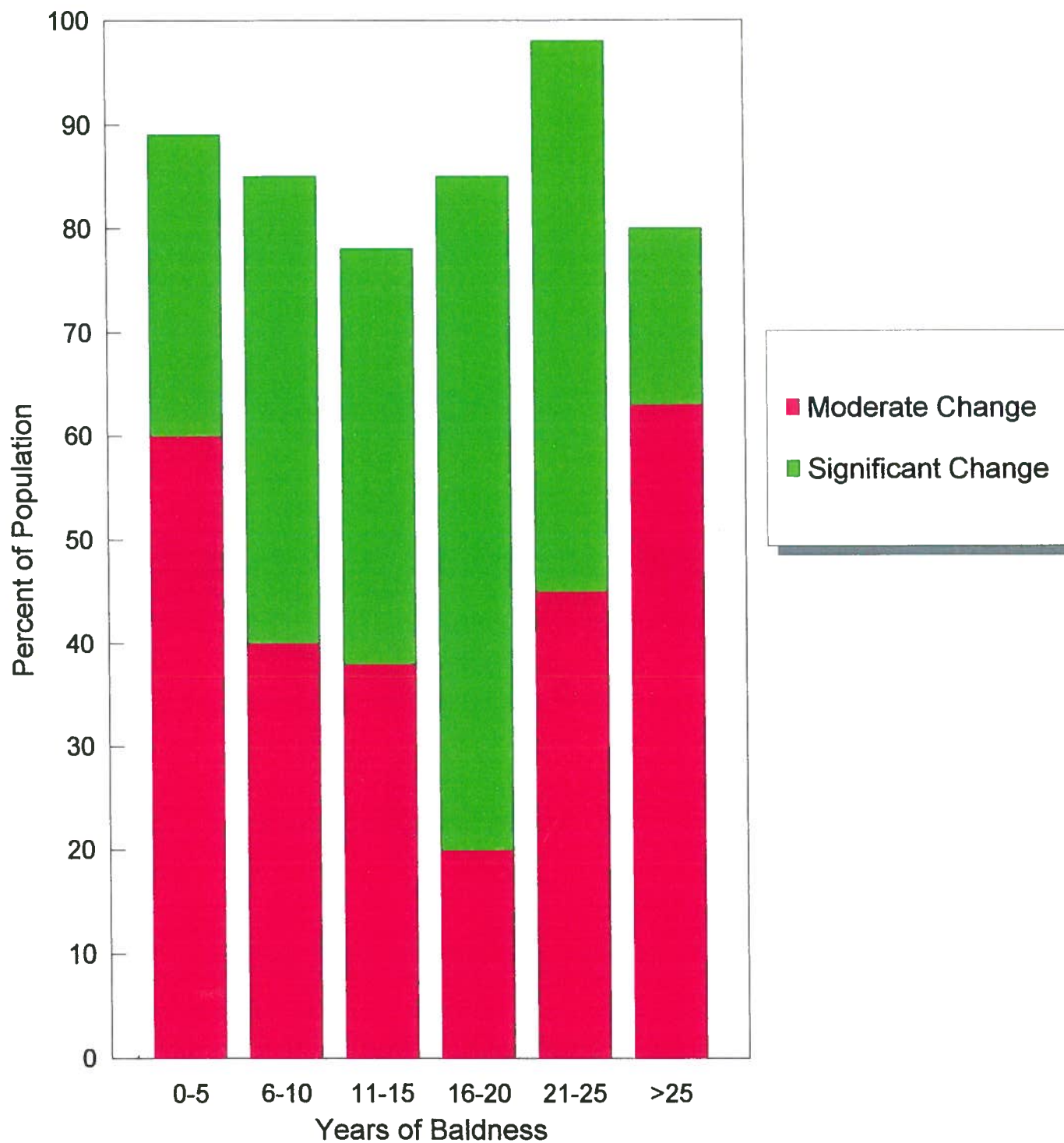
Population Response by Yrs of Baldness
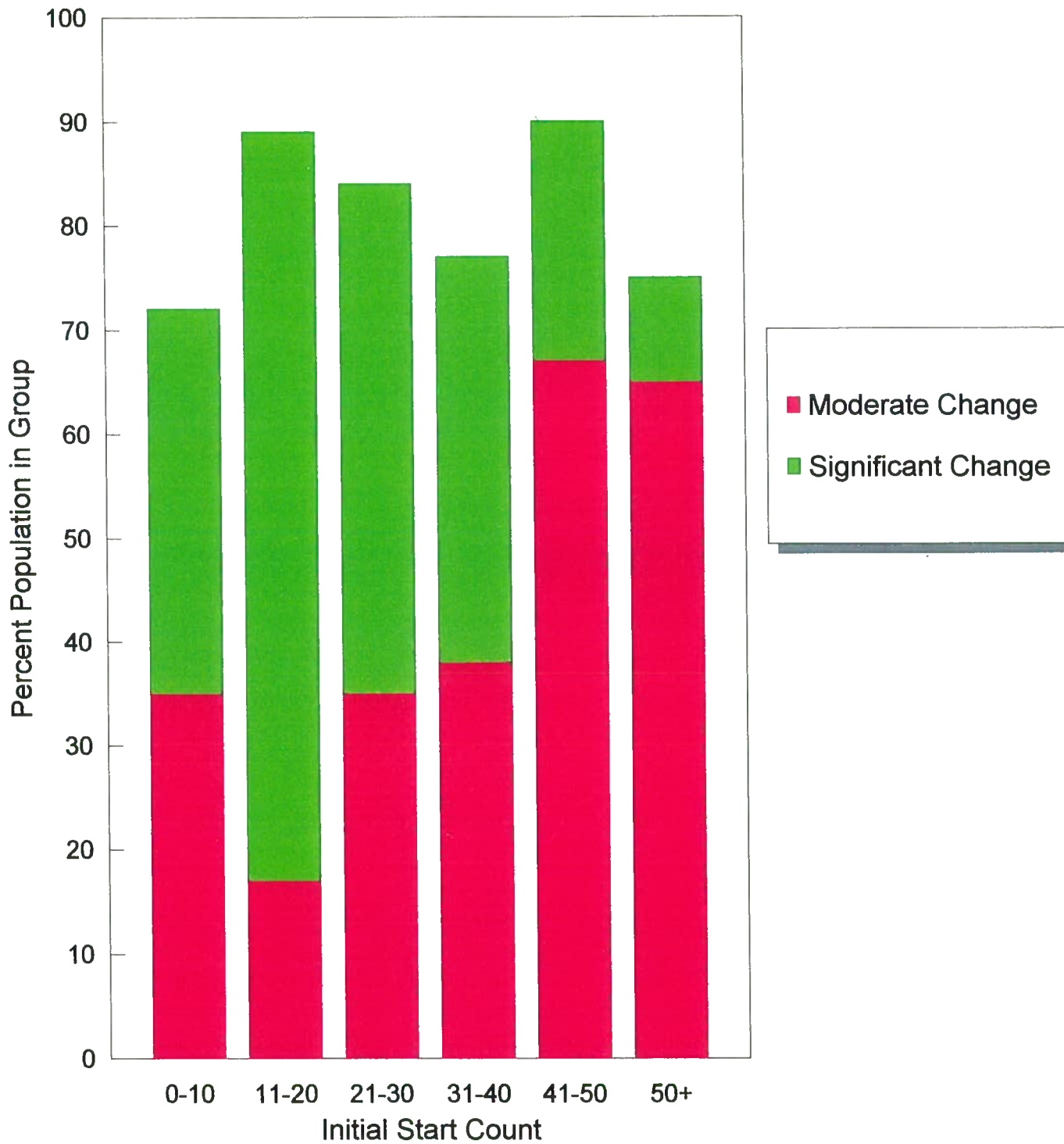
Figure 2

Response by Intitial Start Count

Figure #3

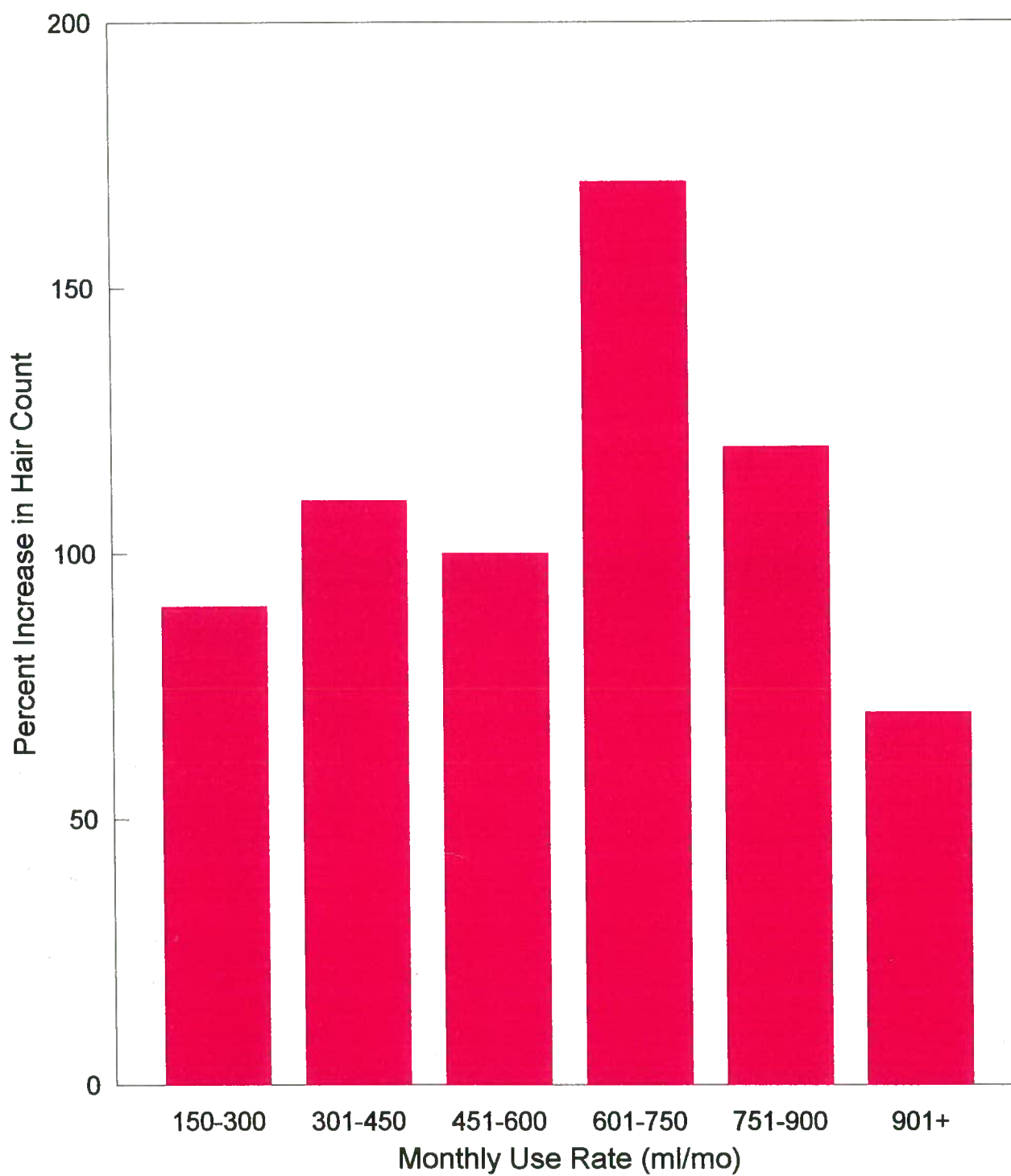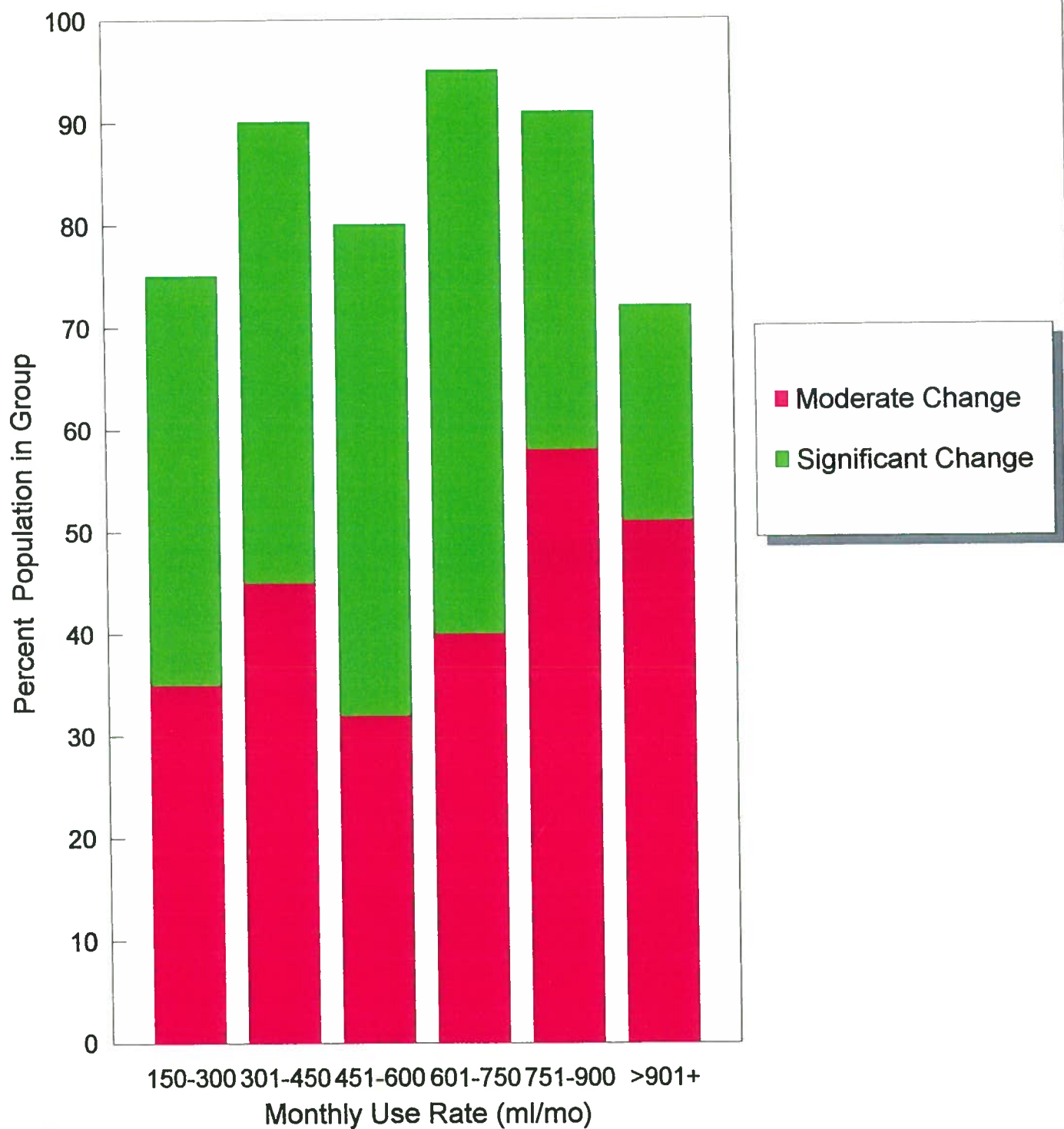Figure #4

Figure #5

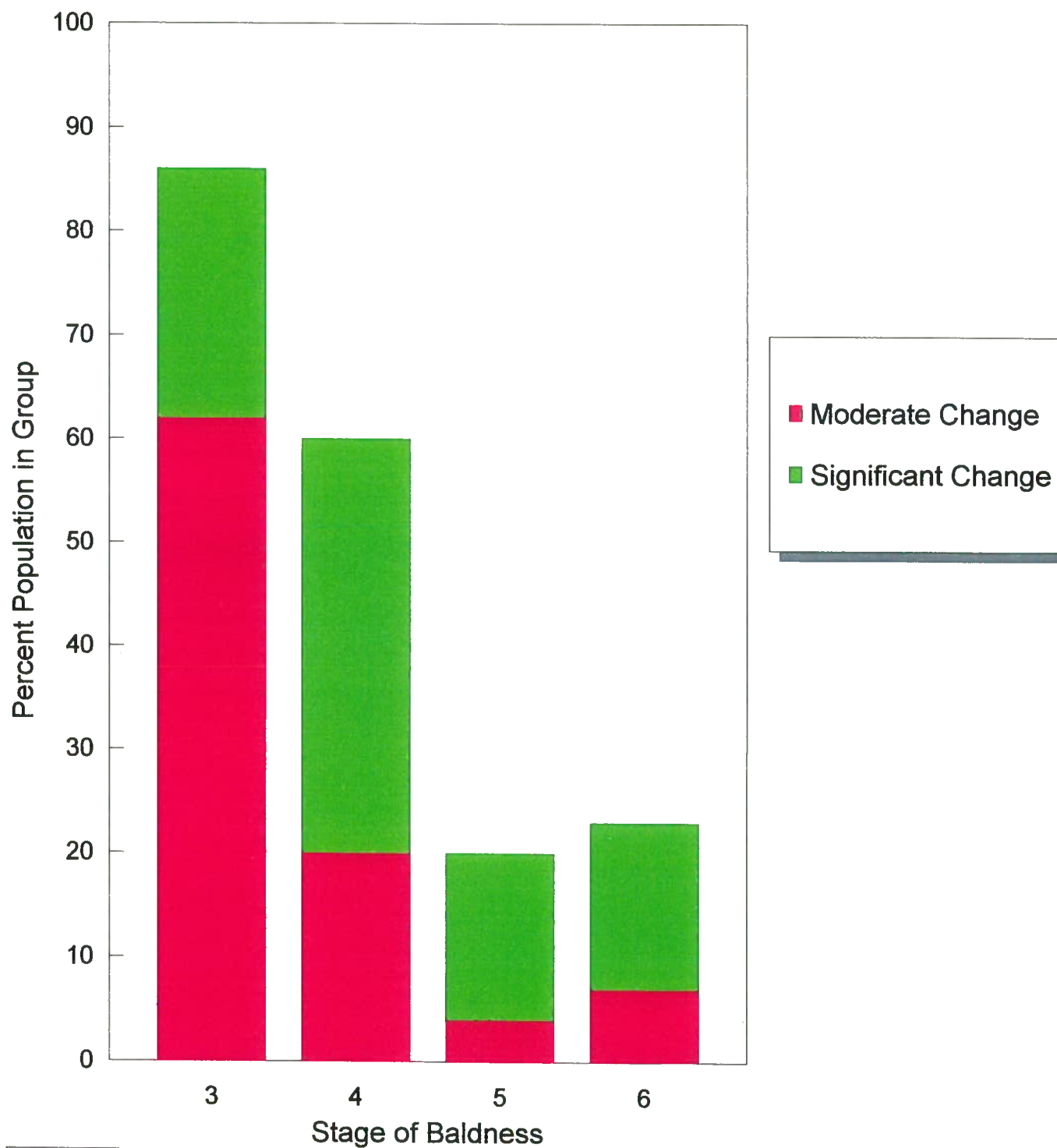Response by Stage of Baldness
Qualitative Data

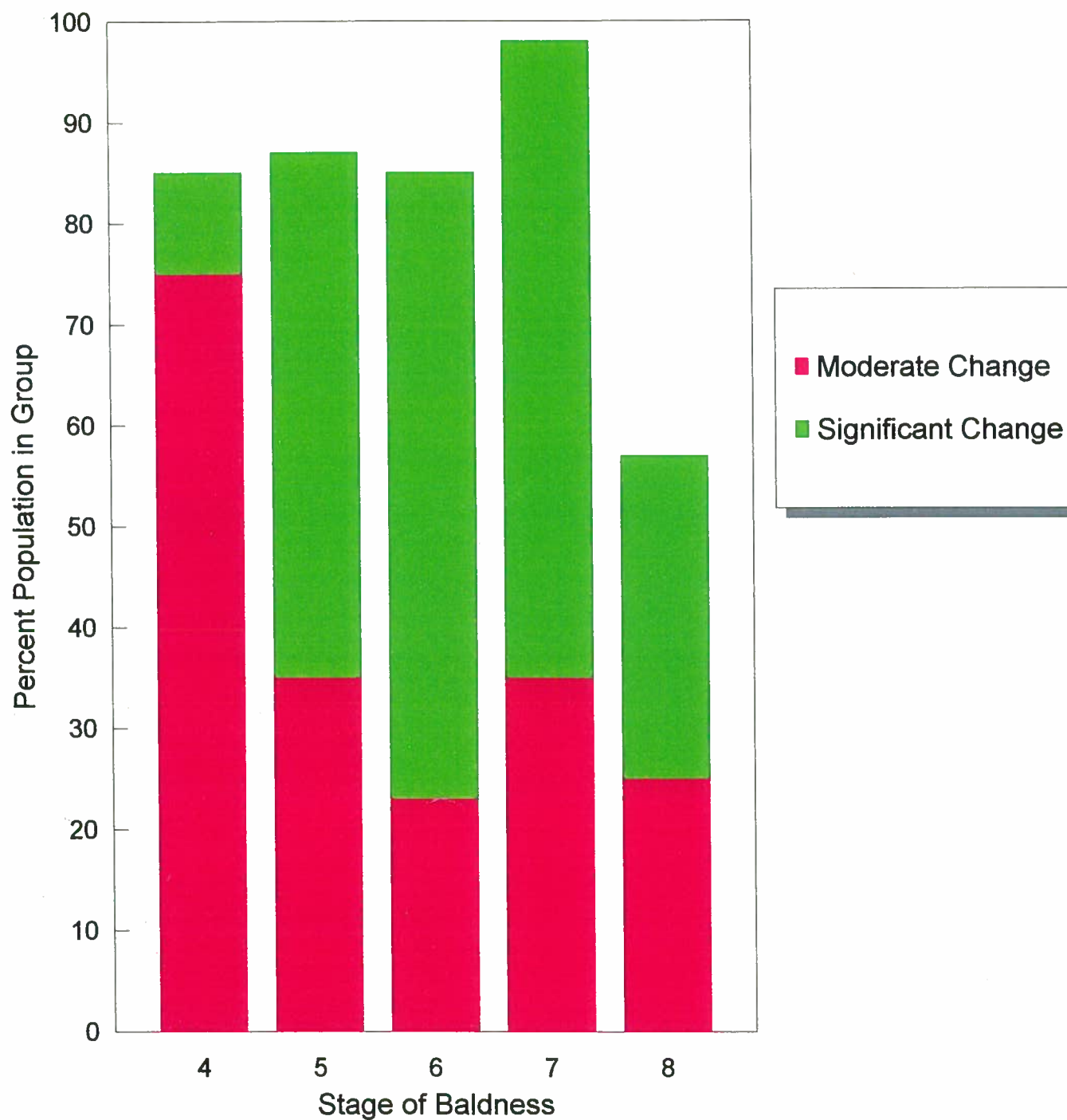Figure #6

Response by Stage of Baldness
Quantitative Data

Figure #7

The following study entitled "Effect of Topical Application of Analog Hair Regrowth ™ Solution on Male Pattern Baldness" has been completed and evaluated on October 26th, 1992. The paper will be submitted for publication with the following individuals as authors:

A. J. Farmilo, Ph. D.

L. E. Fremont, B.Sc. M.D.

M.A. Stratis B.Sc. R.T.

J. S. McGrail, M.D. M.S. F.R.C.S. (C)

Howard Minuk, M.D., F.R.C.P. (C)
A.B.I.M.